

AMENDMENTS TO THE SPECIFICATION:

Amend the paragraph beginning at page 2, line 10 to read as follows:

U.S. Patent Application No. ~~2002/0139008 (the '008 application)~~ 2002/0139088 (the '088 application), published October 3, 2002 also describes a method of producing pre-filled COC syringes in an in-line manufacturing process. In contrast to the '270 patent the process of manufacture may best be described as an aseptic filling process. In the aseptic filling process, the various components are sterilized individually and then brought into a sterile environment through an isolator. In this process, the various components may be sterilized by different means before being transferred into the sterile environment. Once inside the sterile environment, the components may be assembled into a sterile pre-filled syringe that is then transferred out of the sterile environment. After transfer additional packaging steps may be undertaken including insertion and connection of a plunger rod as well as labeling of the syringe and placing in an environmental packaging for handling and shipping.

Amend the paragraph beginning at page 2, line 22 to read as follows:

As explained above, during the syringe assembly, whether it is composed of a glass syringe body or a polymeric syringe body, requires a piston component. In many instances the piston is frequently manufactured of an elastomeric material. The elastomeric material deforms to provide a sterile seal against the inner diameter of the syringe body. The piston is also critical to the operation of syringes, in the aspiration and dispensing of medical fluids. Therefore, it is preferred that the piston provide numerous functional features as it should: (1) be capable of providing a sterile barrier

for the contents of the syringe during the anticipated transport and storage of the syringe, (2) remain lubricious enough during storage such that it may be initially activated without excessive force, sometimes referred to as breakaway force, and then slide easily to provide control to the rate and amount of medical fluid being ejected from the syringe; (3) not leach undesirable extractives from the material comprising the piston into the medical solution; ~~(3)~~ (4) supply a vapor barrier to prevent water loss which could modify the concentrations of the solutions in the syringe; and ~~(4)~~ (5) be capable of being sterilized by methods suitable for commercial production of medical devices. To assist in satisfying the surface lubricity requirement above, prior art devices have employed such methods as coating the piston with a PTFE Teflon coating, or a silicone coating and/or coating the interior of the syringe barrel with a silicone coating. However the PTFE Teflon coating adds extra costs and the silicone lubricant in some instances does not appear to adequately ~~satisfies a~~ satisfy many of the above-noted requirements.

Amend the paragraph beginning at page 14, line 30 to read as follows:

It has been found that altering the geometry of the piston 24 lowers the breakaway forces while still utilizing a silicone coating on the piston. Referring particularly to FIGS. 3, it has been found that to alter the relative geometry of the lobes improves the ability of the piston 24 to provide a sterile seal while utilizing a silicone coating but without generating excessive breakaway forces. In the preferred embodiment a piston 200 is provided with the annular lobes 37, 34 with varying geometries. In a preferred embodiment and in reference to a syringe barrel 14 of a 3

mL syringe defining an internal diameter of 8.75 mm, the annular lobe 37 adjacent the distal end 38 of the piston 24 defines a radius (Rd) that is greater than the radius (Rp) of at least one annular ~~lobe~~ lobe 34 and ~~preferable~~ preferably two annular lobes disposed along the body of the piston 24 which are spaced in the proximal direction along the piston. In one preferred embodiment shown in FIG. 3, the radius (Rp) of the two annular lobes 34 along the body of the piston is approximately 0.375 mm, while the radius (Rd) of the annular ~~lobe~~ lobe 37 adjacent the distal end 38 of the piston is approximately 0.750 mm. The decreased radius 35 of the annular lobes 34 along the body of the piston 24 results in decreased surface contact between the piston and the syringe barrel, and decreased breakaway forces of the piston. To provide additional assistance in decreasing the breakaway forces of the piston the minor diameter of the piston 24 defined at the base of the gap between the annular lobes 34 may be decreased.

Amend CHART 7 at page 17, line 11 to read as follows:

Chart 7		Steam Sterilized/Parylene Coated Piston	
3 mL. syringe barrel		Piston 100 <u>300</u>	Piston 200 <u>400</u>
	Time (T)	Avg. Force F_s (lbs.)	Avg. Force F_s (lbs.)
	T = 0 weeks	21.7 <u>1.7</u>	2.0
	T = 4 weeks	2.2	2.7
	T = 12 weeks	2.3	2.55
	T = 26	2.2	2.6

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Reply to Office Action of February 23, 2006

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